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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,864	BLAKESLEY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10,12-14,16-18,20-27,29,31-37 and 39-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

REASSIGNMENT AFFECTING APPLICATION LOCATION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1654.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STAUS OF THE CLAIMS

2. The amendment and remarks filed 08/23/05 are acknowledged, entered and considered. In view of Applicant's request, claims 1, 12, 13, 20, 41, 42 and 44 have been amended. Claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 are now pending in the application. The rejection under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendment and remarks filed 08/23/05. However, the rejection under 35 U.S.C. 103(a) over the prior art of record is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Condra (U.S. Patent No. 4,973,551) taken with Shah et al (U.S. Patent No. 4,303,530) and Henco et al (U.S. Patent No. 5,652,141).

Applicant's arguments filed 08/23/05 have been fully considered but they are not persuasive. Applicant has argued that to more clearly state the invention, Applicant has amended claim 1 to recite a method for isolating peptides or proteins that comprises contacting cells with a pore containing matrix, adding a lysis/disruption/permeabilization composition to the matrix in a separate step, and causing soluble peptide(s) or protein(s) to flow through the column. This is in contrast to the primary reference of Condra, in which a DE-52 column is used to isolate sporozoites from a preparation of "oocysts", sporocytes, and oocyst shells". Condra does not include a step in which a lysis/disruption/permeabilization composition or compound is added to the matrix "in an amount sufficient to lyse, disrupt, or permeabilize the cells" as recited in claim 1. Further, the cited references either singularly or in combination do not render the claims obvious. To establish a *prima facie* case of obviousness, each and every element of

the claims must be taught or suggested by the references. The primary reference of Condra does not disclose all elements of claims 1, 3, 5-10, 12-14 and 16-18. Applicant maintains that the "separation buffer" of Condra referred to in the Office Action does not constitute a lysis/disruption/permeabilization composition or compound in an amount sufficient to lyse, disrupt or permeabilize the cells as recited in independent claims 1, 20 and 21.

Furthermore, the secondary reference of Shah et al does not provide disclosure of filters with pore sizes that overlap those recited in claims 1, 5, 6, 20, 21 and 41-44. Shah's filter is for isolating cells, not components of cells, and therefore motivation for combining this reference with Condra is lacking. Moreover, the secondary reference of Henco et al discloses an apparatus that comprise a pore-containing matrix that comprises one or more lysis/disruption/permeabilization compositions or compounds an amount sufficient to lyse, disrupt, or permeabilize cells. In Henco, a solution for lysing cells is not provided with the matrix, but is added separately to the apparatus as disclosed on col. 4, lines 66 and 67. Thus, claims 21-27, 29, 31 and 32 are not obvious and Applicant concludes by stating that the rejection should be withdrawn is not persuasive.

Contrary to Applicant's arguments as discussed in the previous Office action, the primary reference of Condra ('551 patent) discloses a method of isolating a protein molecule or a population of protein or peptide molecules by contacting the cells with a matrix such as DE-52 anion exchange column which comprises one or more lysis/disruption/permeabilization composition or compounds in an amount sufficient to

digest (lyses) with proteolytic enzyme, preferably pepsin, disrupt or permeabilize the cells.

With respect to Applicant's arguments that Condra does not include a step in which a lysis/disruption/permeabilization composition or compound is added to the matrix is found to be unpersuasive. Contrary to Applicant's arguments the primary reference of Condra clearly suggests the use of enzymes for lysis/disruption/permeabilization composition, and as such meets the limitations of claims 9 and 10. The isolated cells are separated by gel permeation chromatography, preferably Sephadex S 200 (polysaccharide matrix which is a tube, a bead, and a gel) in a separation buffer comprising one or more detergents. Each preparation is added to the column and eluted with the separation buffer. Thus, the step(s) of adding is disclosed in the reference regardless to the sequence of the step(s) because it would be obvious to one of ordinary skill in the art to reverse the steps since selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690 USPQ 330 (CCPA 1946). See also *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious). Se also MPEP 2144.04(IV,C).

The Examiner acknowledges that the primary reference of '551 patent differs from claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 in not teaching the use of a pore-containing matrix with the pore sizes as claimed and a kit formulation thereof. However, the secondary reference of Shah et al teaches the use of a filter for removing microaggregates from the blood and blood components having a pore size and/or

diameter ranging from 20 to about 400 microns which overlaps with the claimed ranges, and as such meets the limitations of claims 1, 5, 6, 20, 21 and 41-44 (See e.g., cols 1-3). Further, the reference of Henco et al on col. 2 and Figure 1 discloses the use of a device having matrix size from 1 to 50 μm in which the cell immobilized with matrix are lysed using detergent and eluted by adjusting to high ionic strength subsequent to various washing operations. Thus, the secondary reference of Henco et al clearly teaches the use of an apparatus containing a housing, a pore-containing matrix and a chromatographic resin as directed to claims 21-27, 29, 31 and 32.

Therefore, given the teachings of the primary reference of '551 patent, one of ordinary skill in the art would have been motivated at the time the invention was made to adapt the above scheme of using of a pore-containing matrix having the claimed diameter ranges and an apparatus containing a housing, pore-containing matrix and a chromatographic resin. Further, such features are known or suggested in the art, as seen in the secondary references, and including such features into methods and compositions of isolating a protein molecule or a population of protein or peptide molecules by contacting the cells with a matrix which comprises one or more lysis/disruption/permeabilization compositions or compounds in an amount sufficient to lyse, disrupt or permeabilize the cells of the primary reference of '551 patent would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof. Because the primary reference of '551 patent possess the properties of requiring that cells are contacted with a matrix which

comprises one or more lysis/disruption/permeabilization composition or compounds in an amount sufficient to lyse, disrupt or permeabilize the cells.

Thus, in view of the above and in view of the combined teachings of the prior art, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Therefore, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them".

ACTION IS FINAL

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AAMohamed/AAM
October 28, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER